



Verastem Oncology Reports First Quarter 2023 Financial Results and Highlights Recent Company Progress

May 9, 2023

New Data from Interim Analysis of Verastem Oncology's RAMP 201 Trial Evaluating Avutometinib and Defactinib in Recurrent Low-Grade Serous Ovarian Cancer (LGSOC) to be Presented at the American Society of Clinical Oncology Annual Meeting

Studies of Avutometinib Combinations in KRAS G12C Mutant Non-Small Lung Cancer, Pancreatic Cancer and Other RAS Pathway-Driven Cancers Advancing

Strong Financial Position with Company Cash, Cash Equivalents, and Investments of \$111.2 Million as of March 31, 2023

BOSTON--(BUSINESS WIRE)--May 9, 2023-- Verastem Oncology (Nasdaq: VSTM), a biopharmaceutical company committed to advancing new medicines for patients with cancer, today reported financial results for the first quarter ending March 31, 2023, and highlighted recent progress.

"During the first quarter of this year, we announced the positive results from a planned interim analysis of Part A from our RAMP 201 trial in LGSOC. This, combined with a productive meeting with the FDA, has confirmed avutometinib and defactinib as the go-forward treatment regimen and reaffirmed our goal of filing for accelerated approval upon data maturity in the RAMP 201 trial and initiation of a confirmatory study," said Brian Stuglik, Chief Executive Officer of Verastem Oncology. "We believe we are well positioned to deliver on our 2023 goals to initiate a confirmatory study of avutometinib and defactinib in recurrent LGSOC upon agreement with the FDA on study design, advance our KRAS G12C mutant NSCLC program and our frontline metastatic pancreatic cancer and progress our signal-finding, investigator-initiated trial program of combinations with avutometinib in additional RAS pathway-driven cancers with high unmet need."

First Quarter 2023 and Recent Highlights

Low Grade Serous Ovarian Cancer (LGSOC)

- The Company held a productive meeting with the FDA to discuss the encouraging results to date of the ongoing RAMP 201 LGSOC trial evaluating avutometinib ± defactinib among patients with recurrent LGSOC, confirmed the go-forward treatment regimen selection of avutometinib with defactinib based on a planned interim analysis with prespecified criteria and discussed the regulatory path forward.
- Completed enrollment in the primary cohort of 72 patients in the combination arm of RAMP 201. Continued enrollment in the combination arm of RAMP 201 is ongoing to expand the clinical experience in anticipation of initiation of a confirmatory study.
- Announced RAMP 201 abstract highlighting updated interim results from Part A of the ongoing Phase 2, registration-directed RAMP 201 trial has been selected for a presentation in a Poster Discussion Session at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting taking place June 2–6, 2023 in Chicago, IL.
- Launched *Let's Talk About LGSOC*, a new patient initiative that provides detailed information about LGSOC and its symptoms, its differences from the more common high-grade serous ovarian cancer (HGSO), tips and resources, and ways to connect with others in the LGSOC community. The initiative, developed with advocacy groups, clinicians, and patients, serves to bring broader attention to this rare and underserved ovarian cancer.

Other Programs

- In the Company's RAMP 203 and RAMP 204 Phase 1/2 clinical trials, the combinations of avutometinib with Amgen's LUMAKRAS® (sotorasib) (RAMP 203) and with Mirati's KRAZATI® (adagrasib) (RAMP 204) are evaluated in patients with KRAS G12C mutant NSCLC. RAMP 203 progressed to the recommendation of the Phase 2 dose (avutometinib 4 mg BIW PO and sotorasib 960 mg QD PO) and initiation of Part B dose expansion in patients who are G12C inhibitor treatment naïve and in patients who experienced disease progression on prior G12C inhibitor monotherapy. Dose escalation is ongoing in RAMP 204.
- Opened and began enrollment in the Company's RAMP 205 Phase 1b/2 clinical trial evaluating avutometinib and defactinib in combination with standard of care chemotherapy (GEMZAR® (gemcitabine) and ABRAXANE®) in patients with metastatic adenocarcinoma of the pancreas. The trial is supported by the Company's receipt of the first "Therapeutic Accelerator Award" from the Pancreatic Cancer Action Network (PanCAN).
- Opened and began enrollment in two new investigator sponsored trials to support our avutometinib clinical trial program.

One trial investigating the use of avutometinib and defactinib in advanced or recurrent mesonephric gynecologic cancers being conducted by Dr Rachel Grisham at Memorial Sloan Kettering Cancer Center. The other trial, investigating the single-dose brain penetration of either avutometinib or defactinib in glioblastoma patients who are undergoing debulking surgery being conducted by Dr Jeffrey Olson at Emory University.

Corporate Updates

- The Company entered into a definitive agreement to sell up to approximately 2.1 million shares of its Series B convertible preferred stock to affiliates of BVF Partners L.P. in a private placement to raise aggregate gross proceeds of up to approximately \$60 million in two tranches. On January 27, 2023, Verastem Oncology closed on the initial tranche of 1.2 million shares of its Series B convertible preferred stock and received gross proceeds of \$30 million.
- The Company achieved the Term B Milestone pursuant to its credit facility with Oxford Finance LLC and drew down an additional \$15 million in March 2023. Under the credit facility, Verastem can access up to an additional \$110 million in a series of tranches, \$60 million of which are based on certain pre-determined milestones and \$50 million of which are at the lender's discretion.

First Quarter 2023 Financial Results

Verastem Oncology ended the first quarter of 2023 with cash, cash equivalents and investments of \$111.2 million.

Total operating expenses for the three months ended March 31, 2023 (the "2023 Quarter") were \$19.3 million, compared to \$19.6 million for the three months ended March 31, 2022 (the "2022 Quarter").

Research & development expenses for the 2023 Quarter were \$12.0 million, compared to \$13.6 million for the 2022 Quarter. The decrease of \$1.6 million, or 11.8%, primarily resulted from a decrease in drug product and drug substance costs, contract research organization costs, and investigator fees.

Selling, general & administrative expenses for the 2023 Quarter were \$7.3 million, compared to \$5.9 million for the 2022 Quarter. The increase of \$1.4 million, or 23.7%, was primarily related to increased costs associated with financing activities, and additional costs in anticipation of potential launch of avutometinib and defactinib in LGSOC.

Net loss for the 2023 Quarter was \$15.7 million, or \$0.08 per share (basic and diluted), compared to net loss of \$17.0 million, or \$0.09 per share (basic and diluted) for the 2022 Quarter.

For the 2023 Quarter, non-GAAP adjusted net loss was \$17.8 million, or \$0.09 per share (diluted), compared to non-GAAP adjusted net loss of \$15.3 million, or \$0.08 per share (diluted) for the 2022 Quarter. Please refer to the GAAP to Non-GAAP Reconciliation attached to this press release.

Use of Non-GAAP Financial Measures

To supplement Verastem Oncology's condensed consolidated financial statements, which are prepared and presented in accordance with generally accepted accounting principles in the United States (GAAP), the Company uses the following non-GAAP financial measures in this press release: non-GAAP adjusted net loss and non-GAAP adjusted net loss per share. These non-GAAP financial measures exclude certain amounts or expenses from the corresponding financial measures determined in accordance with GAAP. Management believes this non-GAAP information is useful for investors, taken in conjunction with the Company's GAAP financial statements, because it provides greater transparency and period-over-period comparability with respect to the Company's operating performance and can enhance investors' ability to identify operating trends in the Company's business. Management uses these measures, among other factors, to assess and analyze operational results and trends and to make financial and operational decisions. Non-GAAP information is not prepared under a comprehensive set of accounting rules and should only be used to supplement an understanding of the Company's operating results as reported under GAAP, not in isolation or as a substitute for, or superior to, financial information prepared and presented in accordance with GAAP. In addition, these non-GAAP financial measures are unlikely to be comparable with non-GAAP information provided by other companies. The determination of the amounts that are excluded from non-GAAP financial measures is a matter of management judgment and depends upon, among other factors, the nature of the underlying expense or income amounts. Reconciliations between these non-GAAP financial measures and the most comparable GAAP financial measures for the three months ended March 31, 2023, and 2022 are included in the tables accompanying this press release after the unaudited condensed consolidated financial statements.

About Avutometinib (VS-6766)

Avutometinib is a RAF/MEK clamp that induces inactive complexes of MEK with ARAF, BRAF and CRAF potentially creating a more complete and durable anti-tumor response through maximal RAS pathway inhibition. Avutometinib is currently in late-stage development.

In contrast to other MEK inhibitors, avutometinib blocks both MEK kinase activity and the ability of RAF to phosphorylate MEK. This unique mechanism allows avutometinib to block MEK signaling without the compensatory activation of MEK that appears to limit the efficacy of other inhibitors. The U.S. Food and Drug Administration granted Breakthrough Therapy designation for the combination of Verastem Oncology's investigational RAF/MEK clamp avutometinib, with defactinib, its FAK inhibitor, for the treatment of all patients with recurrent low-grade serous ovarian cancer (LGSOC) regardless of KRAS status after one or more prior lines of therapy, including platinum-based chemotherapy.

Verastem Oncology is currently conducting clinical trials with its RAF/MEK clamp avutometinib in RAS- driven tumors as part of its (**Raf And Mek Program**). RAMP 201 is a registration-directed trial of avutometinib in combination with defactinib in patients with recurrent LGSOC. Verastem Oncology has established clinical collaborations with Amgen and Mirati to evaluate LUMAKRAS® (sotorasib) and KRAZATI® (adagrasib) in combination with avutometinib in KRAS G12C mutant NSCLC as part of the RAMP 203 and RAMP 204 trials, respectively. As part of the "Therapeutic Accelerator Award" Verastem Oncology received from PanCAN, Verastem Oncology is conducting RAMP 205, a Phase 1b/2 clinical trial evaluating avutometinib and defactinib with gemcitabine/nab-paclitaxel in patients with front-line metastatic pancreatic cancer.

About Verastem Oncology

Verastem Oncology (Nasdaq: VSTM) is a development-stage biopharmaceutical company committed to the development and commercialization of new medicines to improve the lives of patients diagnosed with cancer. Our pipeline is focused on novel small molecule drugs that inhibit critical signaling pathways in cancer that promote cancer cell survival and tumor growth, including RAF/MEK inhibition and focal adhesion kinase (FAK) inhibition. For more information, please visit www.verastem.com.

Forward-Looking Statements Notice

This press release includes forward-looking statements about Verastem Oncology's strategy, future plans and prospects, including statements related to its financial condition, its potential borrowings, the potential clinical value of various of its clinical trials, the timing of commencing and completing trials, including topline data reports and interactions with regulators. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," "can," "promising" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement.

Applicable risks and uncertainties include the risks and uncertainties, among other things, regarding: the success in the development and potential commercialization of our product candidates, including avutometinib in combination with other compounds, including defactinib, LUMAKRAS® and others; the occurrence of adverse safety events and/or unexpected concerns that may arise from additional data or analysis or result in unmanageable safety profiles as compared to their levels of efficacy; our ability to obtain, maintain and enforce patent and other intellectual property protection for our product candidates; the scope, timing, and outcome of any legal proceedings; decisions by regulatory authorities regarding trial design, labeling and other matters that could affect the timing, availability or commercial potential of our product candidates; whether preclinical testing of our product candidates and preliminary or interim data from clinical trials will be predictive of the results or success of ongoing or later clinical trials; that the timing, scope and rate of reimbursement for our product candidates is uncertain; that third-party payors (including government agencies) may not reimburse; that there may be competitive developments affecting our product candidates; that data may not be available when expected; that enrollment of clinical trials may take longer than expected; that our product candidates will experience manufacturing or supply interruptions or failures; that we will be unable to successfully initiate or complete the clinical development and eventual commercialization of our product candidates; that the development and commercialization of our product candidates will take longer or cost more than planned, including as a result of conducting additional studies; that we or Chugai Pharmaceutical Co., Ltd. will fail to fully perform under the avutometinib license agreement; that we or our other collaboration partners may fail to perform under our collaboration agreements; that we may not have sufficient cash to fund our contemplated operations; that we may be unable to obtain adequate financing in the future through product licensing, co-promotional arrangements, public or private equity, debt financing or otherwise; that Secura will achieve the milestones that result in payments to us under our asset purchase agreement with Secura; that we will be unable to execute on our partnering strategies for avutometinib in combination with other compounds; that we will not pursue or submit regulatory filings for our product candidates; and that our product candidates will not receive regulatory approval, become commercially successful products, or result in new treatment options being offered to patients.

Other risks and uncertainties include those identified under the heading "Risk Factors" in Verastem Oncology's Annual Report on Form 10-K for the year ended December 31, 2022 as filed with the Securities and Exchange Commission (SEC) on March 14, 2023 and in any subsequent filings with the SEC. The forward-looking statements contained in this press release reflect Verastem Oncology's views as of the date hereof, and Verastem Oncology does not assume and specifically disclaims any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

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Condensed Consolidated Balance Sheets

(in thousands)

(unaudited)

	March 31, December 31,	
	2023	2022
Cash, cash equivalents, & investments	\$ 111,204	\$ 87,894
Accounts receivable, net	—	31
Prepaid expenses and other current assets	7,689	4,945
Property and equipment, net	62	92
Right-of-use asset, net	1,645	1,789

Restricted cash and other assets	277	299
Total assets	\$ 120,877	\$ 95,050

Current Liabilities	\$ 22,359	\$ 21,663
Long term debt	39,574	24,526
Lease liability, long-term	1,250	1,470
Preferred stock tranche liability	3,510	—
Convertible preferred stock	21,159	—
Stockholders' equity	33,025	47,391
Total liabilities, convertible preferred stock and stockholders' equity	\$ 120,877	\$ 95,050

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Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

(unaudited)

	Three months ended March 31,	
	2023	2022
Revenue:		
Sale of COPIKTRA license and related assets revenue	\$ —	\$ 2,596
Total revenue	—	2,596
Operating expenses:		
Research and development	12,015	13,642
Selling, general and administrative	7,329	5,934
Total operating expenses	19,344	19,576
Loss from operations	(19,344)	(16,980)
Other income (expense)	(7)	28
Interest income	976	46
Interest expense	(769)	(56)

Change in fair value of preferred stock tranche liability	3,430	—
Net loss	\$ (15,714)	\$ (16,962)
Net loss per share—basic and diluted	\$ (0.08)	\$ (0.09)
Weighted average common shares outstanding used in computing:		
Net loss per share – basic and diluted	200,679	186,264

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Reconciliation of GAAP to Non-GAAP Financial Information

(in thousands, except per share amounts)

(unaudited)

	Three months ended March 31,	
	2023	2022
Net loss reconciliation		
Net loss (GAAP basis)	\$ (15,714)	\$ (16,962)
Adjust:		
Stock-based compensation expense	1,313	1,646
Non-cash interest, net	(36)	17
Change in fair value of preferred stock tranche liability	(3,430)	—
Severance and other	38	—
Adjusted net loss (non-GAAP basis)	\$ (17,829)	\$ (15,299)

Reconciliation of net loss per share

Net loss per share – diluted (GAAP basis)	\$ (0.08)	\$ (0.09)
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Adjust per diluted share

Stock-based compensation expense	0.01	0.01
Non-cash interest, net	—	—
Change in fair value of preferred stock tranche liability	(0.02)	—

Severance and other	—	—
Adjusted net loss per share – diluted		
(non-GAAP basis)	\$ (0.09) \$ (0.08
Weighted average common shares		
outstanding used in computing net loss per share—diluted	200,679	186,264

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Investors:

Dan Calkins
+1 781-469-1694
dcalkins@verastem.com

Nate LiaBraaten
+1 212-600-1902
nate@argotpartners.com

Media:

Lisa Buffington
+1 781-292-4205
lbuffington@verastem.com

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